

## **REMARKS**

### **I. Responses to Examiner's Remarks**

Applicants appreciate the Examiner's careful attention to this application. Reconsideration of the application is respectfully requested. Applicants respectfully request that the basis for all future rejections and objections be stated in subsequent office actions, as opposed to the use of statements such as "for reasons explained in the prior action." As two office actions have been issued, future statements of this nature may fail to clearly state the basis of rejection.

Claims 1-12, 14, 16, 19-29 and 31-35 are pending. Claims 1, 2, 6-12, 14, 21-29 and 31-35 are withdrawn from consideration. Claims were rejected in the Office Action as failing to meet one or more of the requirements of 35 U.S.C. § 112. Applicants are pleased to note that the references identified in the search are considered by the Office to neither anticipate nor render obvious any claim currently under consideration.

### **II. Discussion of Amendments (Support Identified)**

Applicants have made amendments to the claims. Applicants submit that no new matter has been added to the claims. Applicants have made these amendments for the sole purpose of facilitating the expeditious allowance of any subject matter identified as allowable by the Examiner. Applicants make no admission herein that any cancelled or amended claims in their original form is non-patentable, nor do Applicants disclaim the subject matter of any cancelled or amended claims or dedicate them to the public. If any such disclaimers are believed to have been made, Applicants explicitly rescind them for the purpose of future applications to permit recapture of the original subject matter of any

cancelled or amended claims. Applicants reserve the right to file future applications for letters patent directed to the original subject matter of any cancelled or amended claims. Support for the amendments may be found in the specification as originally filed as discussed below.

Claim 19 is amended herein to recite "[[a]] the preparation according to claim 3." The amendment corrects the informal phrase "a preparation according to claim 3." This amendment requires no particular support in the specification.

Claims 20 is amended herein to recite "[[the]] a substrate." This amendment requires no particular support in the specification.

### **III. Interview Summary**

This section serves as Applicants' written statement of the substance of an interview under 37 CFR 1.133(b) and as required by MPEP § 713.04. A telephonic interview was conducted on 13 August 2009. Present were Examiner S. Swope and Applicants' attorney N. Landau. The parties discussed all pending bases for rejection of all independent claims currently under consideration. The parties agreed that the rejection of Claims 3-5 and 16 under 35 U.S.C. § 112 as indefinite for reciting the limitation of "a purified preparation" can be overcome by including a limitation reciting a particular level of purity, for example 30%. The parties agreed that the same amendment would be sufficient to overcome the rejections of Claims 1, 3-5, 16, 19, and 20 under the written description requirement of 35 U.S.C. § 112. The parties agreed that the rejection of Claims 1, 3-5, 16, 19 and 20 under 35 U.S.C. § 112 as non-enabled can be overcome if the proteins LKB1, STRAD, and MO25 are each limited according to the presence of a defined functional structure, the presence of a defined functional sequence, or according

to a given method of isolating the protein. General agreement was reached regarding allowable form of all claims.

#### **IV. CLAIM REJECTIONS**

##### **A. Indefiniteness Rejections Under 35 U.S.C. § 112, Paragraph 2**

On pages 2-4 of the Office Action, Claims 3-5, 16, 19 and 20 were rejected as indefinite on three distinct grounds. Applicants respectfully traverse.

The Office Action states on page 2 that Claims 3-5, 16, 19 and 20 are indefinite because the phrase “A purified preparation, comprising LKB1, STRAD, and recombinant MO25” is not adequately defined. Applicants respectfully disagree, and point out that the terms “purified” and “pure” are defined and discussed at length in paragraphs [0060] through [0063] of the published application. Given this description, one of ordinary skill in the art reading the claims in light of the specification at the time of filing would have understood the metes and bounds of the claims.

The Office Action states on page 3 that Claim 19 is indefinite because Claim 19 recites no steps to test whether or not a compound is effective at modulating LKB1 activity in a cellular context. In response, Applicants point out that the preparations of Claim 3 (recited in Claim 19) may be prepared in some embodiments by preparing a LKB1:STRAD:MO25 complex from an intact cell in which the members of the complex were expressed and assembled. The complex would be expected to retain its activity upon separation from other cellular components once expressed and assembled in the cell.

The Office Action states on page 4 that Claims 19 and 20 are indefinite for recitation of the phrase “a preparation according to claim 3” instead of “the preparation

according to claim 3.” Applicants have amended Claim 19 to correct the rejected language.

The Office Action states on page 4 that Claim 20 is indefinite for recitation of the term “the substrate” without antecedent basis. Applicants have amended Claim 20 to correct the rejected language.

Applicants respectfully request reconsideration of the rejections. As explained above, the claims were not indefinite to one of ordinary skill in the art at the time of filing. Accordingly, Applicants respectfully request withdrawal of the rejections and allowance of the claims.

**B. Enablement Rejections Under 35 U.S.C. § 112 Paragraph 1**

On pages 4-5 of the Office Action, Claims 3-5, 16, 19 and 20 were rejected as non-enabled by the specification. Applicants respectfully traverse.

As noted previously, the specification teaches numerous sequences of LKB1 variants, STRAD variants, and MO25 variants. Given the primary sequence of a polypeptide, it is well within the abilities of one of ordinary skill in the art to make and use the polypeptide without undue experimentation. Accordingly, Applicants respectfully request reconsideration of the claims and withdrawal of the rejections.

**C. Written Description Rejections Under 35 U.S.C. § 112 Paragraph 1**

On page 6 of the Office Action, Claims 3-6, 16, 19 and 20 were rejected under the written description requirement. Applicants respectfully note that the Office has previously taken the position that Claim 6 is withdrawn; Applicants therefore do not address the rejection of Claim 6 on this basis in this response.

The claims are rejected for the stated reason that “the specification fails to disclose the genus of any ‘purified preparation’ comprising any LKB1, STRAD, and MO25 proteins, having any structure, as encompassed by the instant claims, such that the skilled artisan would recognize that Applicants were in possession of the invention at the time of filing.” Applicants respectfully point out that the specification discloses numerous purified preparations comprising the LKB1:STRAD:MO25 complex. The complexes are purified for example through electrophoresis (see paragraph [0165] of the published application), affinity purification (see paragraph [0170] of the published application), and immunoprecipitation (see paragraph [0189] of the published application).

Applicants respectfully request reconsideration of the claims. The claimed embodiments are described sufficiently that one of ordinary skill in the art at the time of filing would have understood that Applicants were in possession of the claimed embodiments. Accordingly, Applicants respectfully request withdrawal of the rejections and allowance of the claims.

## CONCLUSION

The Applicants respectfully request the Commissioner of Patents consider the enclosed remarks and enter the following submission into the record, in response to the Office Action dated 2/25/2009. Reconsideration in light of this submission is respectfully requested. If the Examiner requires additional action that may benefit from a telephone call, Applicants invite a call to its attorney of record, Nicholas J. Landau (Reg. No. 57,120). E-mail correspondence and transactions to [nlandau@babco.com](mailto:nlandau@babco.com) are authorized and encouraged.

Applicants have diligently sought to comply with all requirements and to correct all informalities and rejections. The Application is believed to be in condition for allowance, and a timely Notice of Allowance is respectfully requested.

Respectfully submitted,  
BRADLEY ARANT BOULT CUMMINGS LLP

8/25/2009  
Date

Nicholas J. Landau  
Nicholas J. Landau  
Reg. No. 57,120